### **REMARKS**

Claims 1-8 are pending in the present application. Claim 1 has been amended to correct an obvious typographical error and to more particularly point out and distinctly claim the invention. Support for the claim amendment can be found in paragraphs [0026] and [0048] and in the originally submitted figures. Accordingly, no new matter has been added.

# Rejections Under 35 U.S.C. § 102(b)

Claims 1-8 have been rejected as being anticipated by U.S. Patent No. 5,620,456 ("Sauer et al.", hereinafter "Sauer").

Applicant respectfully traverses the rejection of claims 1-8, and withdrawal of the rejections of claims 1-8 is respectfully requested for at least the following reasons.

#### **Present Invention**

The present invention is directed to a diskectomy instrument 12 including an elongate body 18 having a distal end 12a and a proximal end 12b. The elongate body 18 has a blade opening 27 proximate to the distal end 12a. The diskectomy instrument 12 also includes a blade 26 moveably mounted at least partially within the elongate body 18 proximate the blade opening 27. The blade 26 has a distal end 26a, a proximal end 26b, at least one sharp edge 38 extending at least partially between the distal end 26a and the proximal end 26b, a ramped portion 36 and a stem mating portion 29. The diskectomy instrument 12 also includes a drive stem 21 moveably mounted within the elongate body 18 having a distal end 21a, a proximal end 21b and a blade mating portion 23b, 23c. The drive stem 21 is configured to slideably engage the blade 26 when the drive stem 21 is moved distally thereby extending the blade 26 radially outward through the blade opening 27 and extending the at least one sharp edge toward a radial cutting direction of the diskectomy instrument relative to a longitudinal axis of the diskectomy instrument and the blade mating portion 23b being configured to cooperatively engage the stem mating portion 29 of the blade 26 when the drive stem 21 is moved proximally thereby retracting the blade 26.

As mentioned in the originally submitted specification, at paragraph [0036] for example:

[0036] Fig. 2 shows a side cutaway of the distal end 12a of the diskectomy instrument 12 providing a much more detailed view of the probe assembly 20. The probe assembly 20 includes a probe body 22, a drive stem 21, an inner sheath 24, a biasing cone 25 and at least one blade 26. The probe body 22 includes a blade opening 27 for each blade 26. The blade opening 27 has a distal end 27a and a proximal end 27b. Preferably each blade opening 27 is generally rectangularly-shaped. But, the blade openings 27 may be other shapes. The blade openings 27 are selected to be only slightly wider than the blades 26 in order to provide lateral support to the blades 26 when the blades 26 are radially extended. The close tolerance between the blade openings 27 and the blades 26 also assists in preventing foreign materials from being trapped in between the blades 26 and the blade openings 27 when the blades 26 are being retracted. [underlined emphasis added]

Accordingly, the particular arrangement of the blade extending radially outwardly through the blade openings serves a purpose in a diskectomy instrument in addition to the other patentable features that is not disclosed in the reference relied upon by the Examiner.

Additionally, the original specification at paragraph [0048] discloses that being a diskectomy instrument, the device is configured for rotatable cutting:

[0048] After the blades 26 have been extended, the surgeon rotates the blade rotation knob 16 in either a clockwise or counter-clockwise direction, depending on the direction of the sharpened edge 38 of the blades 26, causing the probe assembly 20 and the associated blades 26 to rotate therewith and providing a rapid debridement of the nucleus pulposus of the intervertebral disk. Unlike conventional prior art curettes and reamers, the curved and outwardly-biased blades 26 (as best shown in Fig. 5) accommodate the natural concavity of the adjacent vertebrae 100 which significantly reduces the amount of time required to enucleate the disk space 121....[underlined emphasis added]

## Sauer

Sauer discloses a trocar assembly having an elongated sleeve 42 (with half sections 44), a rod like drive member 50, a drive collar 52, a pair of pinned cutting blades 82, 83, 122. Each of the various embodiments of cutting blades includes a slot that engages the pin, for example, blades 82, 83 have slots 84, 86 for engaging pins 88, 90 and blades 122 have a singular slot 124

and a singular pin 126. Other embodiments of blades having similar slots and pins are depicted in Figs. 21-24. Generally, Sauer functions by actuating a handle trigger 22 which drives the stem 50 linearly distally through the shaft 94. The pins 88, 90 are fixedly attached to the distal end of the shaft 50. The pin 90 applies forward force on the distal side of arcuate slots 86 and the pin 90 rides through the arcuate slot 86 permitting the blades 82 to move distally and outwardly. When the shaft 50 is moved proximally, the pin 90 applies force to the proximal side of slots 86 thereby retracting the blades 82 proximally and inwardly in a scissor-like motion.

The blades 82 in Sauer move forward or distal to the instrument in a sweeping pattern thereby cutting a linear incision from center outward (i.e., an inverse version of scissors). The sweeping pattern is to cut in advance or distally relative to the instrument and to allow the instrument to advance through tissue. The cuts are made to be very nearly the length of the diameter of the instrument, but the design is <u>not</u> intended to cut or remove or clean any tissue adjacent to the circumference of the instrument since that would defeat the purpose of keeping a "tissue seal" around the cannula assembly 12 which is necessary to maintain carbon dioxide (CO<sub>2</sub>) gas insufflations of peritoneal cavity. (see e.g., col. 10, lines 10-17 "[i]t is desirable that the incision formed in the peritoneal lining be substantially equal to or slightly less than the outer diameter of cannula sleeve 94 such that a fluid tight seal is formed about the cannula sleeve by the adjacent lining tissue defining the opening.").

Sauer's instrument does not extend the blades <u>radially</u> from the tool <u>through the blade</u> opening and <u>extend the at least one sharp edge toward a radial cutting direction of the</u> <u>diskectomy instrument</u> relative to a longitudinal axis of the diskectomy instrument. Rather, the blades of Sauer move forward or distal to the instrument in a sweeping pattern cutting a <u>linear</u> incision distally from center outwardly like an inverse version of scissors, but are disposed forward of the opening in the tool. The sweeping pattern is to cut advance or distal of the instrument and allow the instrument to advance through the tissue. Accordingly, the blades do not <u>extend radially outward through the blade opening</u> and do not <u>extend the at least one sharp edge toward a radial cutting direction of a diskectomy instrument</u> because the blades of Sauer are configured to cut distally (forward of the blades) and not radially.

### Claim 1

Claim 1, as amended, recites, inter alia:

- b) a blade movably mounted at least partially within the elongate body proximate the blade opening, the blade having a distal end, a proximal end, at least one sharp edge extending at least partially between the distal end and the proximal end, a ramped portion and a stem mating portion; and
- c) a drive stem movably mounted within the elongate body having a distal end, a proximal end and a blade mating portion, the drive stem being configured to slidably engage the blade when the drive stem is moved distally thereby extending the blade radially outward thereby extending the blade radially outward through the blade opening and extending the at least one sharp edge toward a radial cutting direction of the diskectomy instrument relative to a longitudinal axis of the diskectomy instrument and the blade mating portion being configured to cooperatively engage the stem mating portion of the blade when the drive stem is moved proximally thereby retracting the blade.

Sauer <u>fails</u> to disclose or suggest a diskectomy instrument having a blade moveably mounted with at least one sharp edge extending at least partially between the distal end and the proximal end, a ramped portion and a stem mating portion and that a drive stem is moveably mounted within an elongate body of the diskectomy instrument and is configured to slideably engage the blade when the drive stem is moved distally <u>thereby extending the blade radially outward through the blade opening and extending the at least one sharp edge toward a radial cutting direction of the diskectomy instrument relative to a longitudinal axis of the diskectomy instrument and the blade mating portion is configured to cooperatively engage the stem mating portion of the blade when the drive stem is moved proximally thereby retracting the blade.</u>

As mentioned above, Sauer's instrument does <u>not</u> extend the blades <u>radially</u> from the tool through the blade opening and does not <u>extend the at least one sharp edge toward a radial</u> <u>cutting direction of a diskectomy instrument</u>. Rather, the blades of Sauer move forward or distal to the instrument in a sweeping pattern cutting a <u>linear</u> incision distally from center outwardly like an inverse version of scissors, but are disposed forward of the opening in the tool. The

sweeping pattern is to cut advance or distal of the instrument and allow the instrument to advance through the tissue. To extend the blades radially outward (i.e., beyond the dimension of the housing) the blades of Sauer are disposed distally outward from the outer shaft 80. The sweeping pattern is to cut advance or distal of the instrument and allow the instrument to advance through the tissue. Accordingly, the blades do <u>not extend radially outward through the blade opening</u> and do <u>not extend the at least one sharp edge toward a radial cutting direction of a diskectomy instrument</u> because the blades of Sauer are configured to cut distally (forward of the blades) and not radially.

A claim is anticipated under 35 U.S.C. § 102 only if <u>each</u> and <u>every</u> element as set forth in the claim is found expressly or inherently described in a single prior art reference and the elements must be arranged as required in the claim. M.P.E.P. § 2131.

Sauer <u>fails</u> to disclose or suggest a diskectomy instrument having a blade that is caused to <u>move radially outwardly through a blade opening and to extend the at least one sharp edge</u> toward a radial cutting direction of the diskectomy instrument, as set forth in claim 1, as amended. It is therefore, respectfully submitted, that independent claim 1 is <u>not</u> anticipated by Sauer because Sauer does not disclose or suggest <u>each</u> and <u>every</u> element of claim 1. Claims 2-8 depend from amended claim 1. Accordingly, applicant respectfully requests that the rejection of amended independent claim 1 and dependent claims 2-8 under 35 U.S.C. § 102(b) be withdrawn.

# **CONCLUSION**

In view of the foregoing amendment and Remarks, it is respectfully submitted that the present application, including claims 1-8, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

WALTER W. ECKMAN

February 18, 2005 By: (Date)

JOHN D. SIMMONS

Registration No. 52,225

AKIN GUMP STRAUSS HAUER & FELD LLP

One Commerce Square

2005 Market Street, Suite 2200 Philadelphia, PA 19103-7013 Telephone: 215-965-1200

Direct Dial: 215-965-1268

Facsimile: 215-965-1210

JDS:cmb

E-Mail: jsimmons@akingump.com